IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

THIS DOCUMENT RELATES TO THE FOLLOWING CASE:

Ramona Winebarger & Rex Winebarger
v. Boston Scientific Corp. No. 2:13-cv-28892

MEMORANDUM OPINION AND ORDER
(*Defendant's Motion for Summary Judgment*)

Pending before the court is defendant Boston Scientific Corporation's ("BSC") Motion for Summary Judgment against Plaintiffs Ramona Winebarger and Rex Winebarger ("Mot. for Summ. J.") [Docket 38]. As set forth below, BSC's Motion for Summary Judgment is **GRANTED IN PART** with respect to Ms. Winebarger's claims for strict liability for manufacturing defect, strict liability for design defect, strict liability for failure to warn, negligent manufacturing, breach of implied warranty of fitness for a particular purpose, breach of implied warranty of merchantability, and fraudulent concealment. BSC's Motion for Summary Judgment is **DENIED IN PART** with respect to Ms. Winebarger's claims for negligent failure to warn, negligent design, and breach of express warranty, and Mr. Winebarger's claim for loss of consortium.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ

prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 70,000 cases currently pending, approximately 15,000 of which are in the BSC MDL, MDL 2326. In an effort to efficiently and effectively manage this massive MDL, I decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled on all *Daubert* motions, summary judgment motions, and motions *in limine*, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a "wave" of cases to be prepared for trial and, if necessary, remanded. (*See* Pretrial Order # 65, *In re: Boston Scientific Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002326, entered Dec. 19, 2013, *available at* http://www.wvsd.uscourts.gov/MDL/boston/orders.html). This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. The Winebargers' case was selected as a Wave 2 case by the defendant.

Plaintiff Ramona Winebarger was surgically implanted with the Uphold Vaginal Support System ("Uphold") on August 17, 2010. (BSC's Mot. for Summ. J. & Mem. of Law in Supp. ("Mem. in Supp.") [Docket 38], at 2). She received the surgery at a hospital in Statesville, North Carolina. (*Id.*). Ms. Winebarger claims that as a result of implantation of the Uphold, she has experienced multiple complications. (*Id.*). She brings the following claims against BSC: strict liability for design defect, manufacturing defect, and failure to warn; negligence; breaches of express and implied warranties; and punitive damages. (Short Form Compl. [Docket 1] ¶ 13). Mr. Winebarger brings a claim for loss of consortium. (*Id.*). In the instant motion, BSC moves for summary judgment on the grounds that "[p]laintiffs legal theories are without evidentiary or legal support." (Mem. in Supp. [Docket 38], at 1).

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor." *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases such as this. The choice of law for these pretrial motions depends on whether they involve

federal or state law. "When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation." *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, however, as the Winebargers did in this case, I consult the choice-of-law rules of the state in which the implantation surgery took place. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) ("For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product."). Ms. Winebarger received the implantation surgery in North Carolina. Thus, the choice-of-law principles of North Carolina guide this court's choice-of-law analysis.

The parties agree, as does this court, that these principles compel application of North Carolina law. North Carolina generally applies the *lex loci delicti* approach, which provides that

"the state where the injury occurred is considered the situs of the claim." *Harco Nat'l Ins. Co. v. Grant Thornton LLP*, 698 S.E.2d 719, 722–23 (N.C. App. 2010). Here, the alleged injury occurred in North Carolina, where Ms. Winebarger was implanted with the allegedly defective device. Thus, I apply North Carolina's substantive law to this case.

III. Analysis

BSC argues that it is entitled to summary judgment in this case because the Winebargers' claims lack either evidentiary or legal support. The plaintiffs agree that this court should dismiss Ms. Winebarger's claims for strict products liability, negligent manufacture, breach of implied warranty, and fraudulent concealment. (Pls.' Resp. in Opp'n to BSC's Mot. for Summ. J. & Mem. of Law in Supp. ("Resp. Mem. in Supp.") [Docket 59], at 1 n.1). Therefore, BSC's Motion for Summary Judgment on Ms. Winebarger's claims for strict products liability, negligent manufacture, breach of implied warranty, and fraudulent concealment is **GRANTED**. Below, I apply the summary judgment standard to each remaining claim.

A. Negligent Failure to Warn

Under North Carolina law, "[n]o manufacturer . . . shall be held liable in any product liability action for a claim based upon inadequate warning or instruction unless the claimant" can satisfy three requirements. N.C. Gen. Stat. § 99B-5(a). First, the claimant must establish "that the manufacturer . . . acted unreasonably in failing to provide such warning or instruction." *Id.* Second, the claimant must establish "that the failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought." *Id.* Finally, the claimant must establish either of the following:

> (1) At the time the product left the control of the manufacturer . . ., the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer . . . knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable

> claimant[; or] (2) After the product left the control of the manufacturer . . . , the manufacturer or seller became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

Id.

BSC first argues that, under subsection (c) of the same statute, the learned intermediary doctrine shields it from liability. (Mem. in Supp. [Docket 38], at 2 (citing N.C. Gen. Stat. § 99B-5(c))). Subsection (c) provides: "[N]o manufacturer . . . shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant . . . ."

While I am not persuaded that the plain language of subsection (c) provides the basis for application of the learned intermediary doctrine to the instant case, "[t]here are indications that North Carolina courts would adhere to the learned intermediary doctrine" in matters of product liability. *Baraukas v. Danek Med., Inc.*, No. 6:97CV00613, 2000 WL 223508, at *4 (M.D.N.C. Jan. 13, 2000) (citing *Foyle ex rel. McMillan v. Lederle Labs.*, 674 F. Supp. 530, 535–36 (E.D.N.C. 1987)). In fact, in *Baraukas*, the United States District Court for the Middle District of North Carolina determined that the learned intermediary doctrine applied where the manufacturer warned the plaintiff's physician about bone screws. *Id.* Accordingly, consistent with the courts that have addressed this issue before me, I assess Ms. Winebarger's negligent failure to warn claim under the learned intermediary doctrine.

BSC argues that Ms. Winebarger's failure to warn claim fails because BSC "provided clear warnings of the risks associated with the Uphold" to Dr. Coryell, the implanting physician. (Mem. in Supp. [Docket 38], at 8). In support, BSC references the Uphold Vaginal Support

System Directions for Use ("Uphold DFU"), which advised Dr. Coryell of potential complications including dyspareunia, pain, and constipation. (Uphold DFU [Docket 38-7], at 3–4). While BSC's reference to the Uphold DFU is accurate, North Carolina law requires that a manufacturer "execute the '*highest*' or '*utmost*' caution, commensurate with the risks of serious harm involved, in the production of a dangerous instrumentality or substance." *Ziglar v. E.I. du Pont de Nemours & Co.*, 280 S.E.2d 510, 515 (N.C. App. 1981) (emphasis added). Furthermore, a manufacturer's warnings must be "sufficiently intelligible and prominent to reach and protect all those who may reasonably be expected to come into contact with [the product]." *Id.* at 516 (citing Prosser, *Handbook of the Law of Torts* 96, 99 (4th ed. 1971)).

Here, a genuine dispute of material fact exists with regard to whether BSC executed the highest or utmost caution. First, as the Winebargers point out, the Uphold DFU failed to represent information regarding (1) the contraction rate of the mesh and (2) the dangers of implanting polypropylene into the human body. (*See* Uphold DFU [Docket 59-1]). With regard to the contraction rate of mesh, the evidence demonstrates that BSC was internally aware of the clinical significance of such rates, (*see* Memo from Jim Goddard to Al Intoccia, et al. (Nov. 25, 2008) [Docket 59-4]), but failed to convey such information, through the Uphold DFU, to Dr. Coryell. (*See* Uphold DFU [Docket 59-1]; *see also* Coryell Dep. [Docket 59-2], at 83:2–83:24; 84:20–85:8; 85:13–85:19; 86:9–86:12; 99:6–99:18). Additionally, although the 2004 Material Data Safety Sheet ("MSDS") issued by BSC's supplier of polypropylene warned BSC not to implant the material into the human body, (2004 MSDS [Docket 59-5]), the Uphold DFU did not pass on such a warning.[1] (Uphold DFU [Docket 59-1]). Accordingly, in light of this evidence, a

[1] BSC argues that the MSDS is hearsay and therefore must be discarded in ruling on this motion. As I determined in *In re C. R. Bard, Inc., Pelvic Repair Sys. Products Liab. Litig.*, No. 2:10-CV-01224, 2013 WL 3282926, at *3 (S.D. W. Va. June 27, 2013), however, "[t]he MSDS falls within the hearsay exception found in Rule 803(17) as an 'other

reasonable juror could conclude that BSC failed to "execute the 'highest' or 'utmost' caution, commensurate with the risks of serious harm involved, in the production of" the Uphold. *Ziglar*, 280 S.E.2d at 515.

BSC also argues that Ms. Winebarger cannot avoid the preclusive effect of the learned intermediary doctrine because reliance is required to establish causation. BSC specifically contends that Dr. Coryell did not rely on the Uphold DFU in her treatment of Ms. Winebarger. (Reply Mem. in Supp. [Docket 68], at 3–7). Contrary to BSC's argument, Dr. Coryell explicitly testified that it was "fair" to state that the Uphold DFU was "something [she] *relied* on as part of informing [herself] what the risks and benefits of the product are . . . ." (Coryell Dep. [Docket 59-2], at 70:7–70:18) (emphasis added). Unlike the facts in *Lewis v. Ethicon Inc.*, No. 2:12-cv-4301, 2014 WL 186869, at *4 (S.D. W. Va. Jan. 15, 2014), *rev'd in part on other grounds*, No. 2:12-cv-4301, 2014 WL 457551 (S.D. W. Va. Feb. 3, 2014), and *Jones v. C. R. Bard, Inc.*, No. 2:11-cv-00114, 2013 WL 5591948, at *6 (S.D. W. Va. June 4, 2013), the facts here provide evidence that Dr. Coryell relied on the Uphold DFU. (*See* Coryell Dep. [Docket 59-2], at 70:7–70:18). In turn, a reasonable juror could determine that BSC's allegedly defective warnings proximately caused Ms. Winebarger's injuries. *See Bryant v. Adams*, 448 S.E.2d 832, 843 (N.C. App. 1994) ("The issue of proximate cause is usually a question for the jury, . . . and the question of inadequate warning as proximate cause has been specifically found by this [c]ourt to be legally sufficient to reach the jury.").

Therefore, BSC's Motion for Summary Judgment on Ms. Winebarger's negligent failure to warn claim is **DENIED**.

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compilation[] that [is] generally relied on by the public or by persons in particular occupations.'" Furthermore, "the MSDS falls within the residual hearsay exception under Rule 807." *Id.*

B. Negligent Design

Under North Carolina law, a plaintiff alleging inadequate design first must prove "that at the time of its manufacture the manufacturer acted unreasonably in designing or formulating the product, [and] that this conduct was a proximate cause of the harm for which damages are sought . . . ." N.C. Gen. Stat. § 99B-6(a). Additionally, a plaintiff must prove one of the following:

> (1) At the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product[; or] (2) At the time the product left the control of the manufacturer, the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design.

Id.

BSC argues that Ms. Winebarger lacks evidence demonstrating the following: (1) that BSC acted unreasonably in designing the Uphold; and (2) that BSC failed to adopt a reasonable alternative design. (Mem. in Supp. [Docket 38], at 12–13). Accordingly, I analyze these two issues separately.

To determine whether BSC acted unreasonably in designing the Uphold, North Carolina requires that "the factors to be considered . . . include, but are not limited to, the following":

> (1) The nature and magnitude of the risks of harm associated with the design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product[;] (2) The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm[;] (3) The extent to which the design or formulation conformed to any applicable government standard that was in effect when the product left the control of its manufacturer[;] (4) The extent to which the labeling for a prescription or nonprescription drug approved by the United States Food and Drug Administration conformed to any applicable government or private standard that was in effect when the product left the control of its manufacturer[;] (5) The utility of the product, including the performance, safety, and other advantages associated with that design or formulation[;] (6) The technical, economic, and

> practical feasibility of using an alternative design or formulation at the time of manufacture[;] (7) The nature and magnitude of any foreseeable risks associated with the alternative design or formulation.

N.C. Gen. Stat. § 99B-6(b). BSC argues that the fact that BSC received FDA clearance is, on its own, enough evidence to foreclose the possibility that a reasonable juror could determine that BSC acted unreasonably in designing the Uphold. (Mem. in Supp. [Docket 38], at 12). Ms. Winebarger, on the other hand, points to BSC's alleged knowledge of the dangers of synthetic polypropylene, specifically those documented in medical literature and various export reports. (Resp. Mem. in Supp. [Docket 59], at 7–9).

Before delving into the issue of whether a reasonable juror could determine from such evidence that BSC acted unreasonably in designing the Uphold, I note that I have previously held that 510(k) clearance from the FDA is not relevant to state tort law. *See, e.g.*, *Sanchez v. Boston Scientific Corp.*, No. 2:12-CV-05762, 2014 WL 4059214, at *15 (S.D. W. Va. Aug. 18, 2014); *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 753–56 (S.D. W. Va. 2014); *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL 2187, 2013 WL 3282926, at *2 (S.D. W. Va. June 27, 2013). Thus, without any additional argument in support of its position that BSC did not act unreasonably in designing the Uphold, BSC has failed to "show that there is no genuine issue as to any material fact." *See* Fed. R. Civ. P. 56(a).

BSC next argues that Ms. Winebarger cannot offer substantial evidence that BSC failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design. Ms. Winebarger, however, offers evidence suggesting that a different mesh prototype was offered to BSC two years before Ms. Winebarger's surgery. (Resp. Mem. in Supp. [Docket 59], at 10–11 (citing Letter from Peter H. Gingras, Managing Partner, Proxy Biomedical Ltd., to James Goddard, BSC (Oct. 24. 2008) [Docket 59-18])). Furthermore, Ms. Winebarger demonstrates that BSC was

cognizant of the benefits of a lighter mesh, (Resp. Mem. in Supp. [Docket 59], at 11 (citing Memo from Jim Goddard to Al Intoccia, et al. (Nov. 25, 2008) [Docket 59-4])), including the expectation that "less mesh leads to less inflammation which leads to better outcomes (less dyspareunia, less erosions, less PP degradation over time)." (Resp. Mem. in Supp. [Docket 59], at 11 (citing E-mail from John Sherry to Abby Fischer, et al. (May 29, 2009, 1:17 AM) [Docket 59-10])). Accordingly, a reasonable juror could determine that BSC failed to adopt a reasonable alternative design.

Therefore, BSC's Motion for Summary Judgment on Ms. Winebarger's negligent design claim is **DENIED**.

C. Breach of Express Warranty

Under section 25-2-313 of the North Carolina General Statutes, express warranties are created by the seller in the following ways:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise[;] (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description[;] (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

Accordingly, as BSC argues, any actionable express warranty under North Carolina law must be regarding a statement that is the "basis of the bargain."

BSC first argues that because Ms. Winebarger herself did not receive any materials from BSC—regardless of whether the implanting physician did—she could not have relied on any statement regarding the Uphold. (Mem. in Supp. [Docket 38], at 15–16). But, after Ms. Winebarger pointed to North Carolina law demonstrating that she need not prove contractual privity for her express warranty claim to survive, (Resp. Mem. in Supp. [Docket 59], at 11

(citing *Alberti v. Manufactured Homes, Inc.*, 407 S.E.2d 819 (N.C. 1991)), BSC revises its position and argues that Ms. Winebarger only relied on Dr. Coryell's medical judgment in deciding on the Uphold—and not any express warranty from BSC that might have flowed through Dr. Coryell to Ms. Winebarger. In reviewing the facts before me in the light most favorable to Ms. Winebarger, the facts are not as unequivocal as BSC claims them to be.

Contrary to BSC's argument that Ms. Winebarger failed "to forecast any evidence of reliance," (Reply Mem. in Supp. [Docket 68], at 12), Ms. Winebarger testified that Dr. Coryell represented to her that the Uphold mesh was "new and . . . different" and that, in response to Dr. Coryell's representation, Ms. Winebarger "trusted her." (Winebarger Dep. [Docket 59- 21], at 66:24–67:1). Importantly, even if Ms. Winebarger merely relied on Dr. Coryell's medical judgment in deciding to have the Uphold implanted, a reasonable juror could find that Ms. Winebarger, naturally, relied on the express warranties of BSC as were provided to Dr. Coryell, which formed the basis for Dr. Coryell's medical judgment. *Cf. Michael v. Wyeth, LLC*, No. CIV.A. 2:04-0435, 2011 WL 2150112, at *9 (S.D. W. Va. May 25, 2011) (denying summary judgment on breach of express warranty because even though "plaintiff testified that she did not rely on any statements made by defendants . . . she did rely upon her doctors' recommendations," and as a result, "a presumption arises that [manufacturer's] affirmations were at least part of the 'basis of the bargain' that led plaintiff to ingest [the] drugs"); *Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 972 (E.D. Wis. 2009) (denying summary judgment on express warranty claim where plaintiff did not read drug manufacturer's labeling but relied upon doctor's recommendations, and holding that "a reasonable jury could find that [defendant's] representations to Dr. Todd, which were then communicated to the [plaintiffs], constitute an

affirmation forming a 'basis of the bargain' for [plaintiff's] use of Paxil."); *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602, 625 (E.D. Pa. 2008) (same).

Therefore, BSC's Motion for Summary Judgment on Ms. Winebarger's breach of express warranty claim is **DENIED**.

D. Loss of Consortium

Because Mr. Winebarger's claim for loss of consortium is derivative of Ms. Winebarger's claims, *Stokes v. Se. Hotel Props., Ltd.*, 877 F. Supp. 986, 1000–01 (W.D.N.C. 1994), and at least one of Ms. Winebarger's claims survives, BSC's Motion for Summary Judgment on Mr. Winebarger's claim is **DENIED.**

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that BSC's Motion for Summary Judgment [Docket 38] be **GRANTED IN PART** with respect to Ms. Winebarger's claims for strict liability for manufacturing defect, strict liability for design defect, strict liability for failure to warn, negligent manufacturing, breach of implied warranty of fitness for a particular purpose, breach of implied warranty of merchantability, and fraudulent concealment, and **DENIED IN PART** with respect to Ms. Winebarger's claims for negligent failure to warn, negligent design, and breach of express warranty, and Mr. Winebarger's claim for loss of consortium.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: April 1, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE